IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **ALL PLAINTIFFS LISTED IN PLAINTIFFS' NOTICE OF ADOPTION**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF DR. DOUGLAS GRIER, M.D.

Plaintiffs submit the following reply to Ethicon's Memorandum in Opposition to Plaintiffs' Motion to Exclude the Opinion Testimony of Douglas Grier, M.D. For the following reasons, Ethicon's opposition should be denied and the opinions offered by Dr. Grier should be excluded in their entirety as set forth in whole in Plaintiffs' Memorandum to Exclude the Opinions and Testimony of Douglas Grier, M.D.

ARGUMENT

I. Dr. Grier should be precluded from testifying about the safety and efficacy of the TVT and Prolift Product designs.

Plaintiffs moved to exclude the design opinions of Dr. Grier in their Wave 1 Memorandum.[1] In ruling on the Wave 1 Motion regarding Dr. Grier, this Court interpreted the term "design" to refer to "opinions about the process of designing a product. Opinions of this sort include, for example, opinions about pre-market product testing and product development."[2]

[1] *See* Ex. A, Plaintiffs' Wave 1 Memorandum in Support of Their Motion to Exclude Certain Opinions and Testimony of Douglas Grier, M.D.
[2] Mem. Op. and Order (*Daubert* Motion re: Douglas Grier, M.D.), No. 2:12-md-02327, at 6-7 (S.D. W. Va. Aug. 31, 2016) [ECF # 2703].

Upon review, the Court found that Dr. Grier had not expressed any opinions specifically regarding designing a product, and therefore Plaintiffs' Motion was denied as moot.[3]

Plaintiffs' challenge to Dr. Grier's design testimony does not specifically focus on the actual process of designing a product. Rather, Plaintiffs specifically challenge Dr. Grier's qualifications and methodology regarding his testimony on the safety and efficacy of the TVT and Prolift designs.[4] In his Prolift report in this litigation, Dr. Grier includes a section titled "VI. The Design of Prolift" with a subsection titled "The Usefulness, Desirability, and Safety of the Prolift Device."[5] In this section, Dr. Grier offers expert opinions about specific design features of the Prolift device which contribute to the safety of the device.[6] For example, in this section, Dr. Grier opines that specific mesh design properties, such as the "lightweight, large-pore, knitted, monofilament" mesh contribute to the safety of the mesh.[7] Dr. Grier's opinions regarding the safety and efficacy of the design of the Prolift and TVT mesh should be excluded for the reasons stated in Plaintiffs' original Memorandum. To the extent necessary, the Plaintiffs incorporate their Wave 1 Memorandum as Exhibit A.

II. In Wave 1 this Court excluded Dr. Grier's expert testimony about product warnings and the result here should be the same.

This Court recently excluded Dr. Grier's expert testimony about product warnings, which includes expert testimony about the adequacy of the relevant IFU. Mem. Op. and Order (*Daubert* Motion re: Douglas Grier, M.D.), No. 2:12-md-02327, at 7-8 (S.D. W. Va. Aug. 31, 2016) [ECF # 2703] ("Dr. Grier does not possess the additional expertise to offer expert testimony about what an IFU should or should not include. Accordingly, Dr. Grier's expert

[3] *Id*. at 7.
[4] Ethicon has stated that "[t]o the extent Plaintiffs challenge Dr. Grier's qualifications and methodology regarding his testimony on the *safety* and *efficacy* of the TVT and Prolift designs, Ethicon incorporates and adopts its Opposition to Plaintiffs' Wave 1 motion." Defs' Brf. at 2.
[5] Ex. B, Dr. Grier Prolift Report at 22-24; *see also* Ex. C, Dr. Grier TVT and TVT-O Report at 25-30.
[6] *Id.*
[7] *Id*.

testimony about these matters is **EXCLUDED**."). The Court's ruling here should be no different.

In excluding Dr. Grier's warnings testimony, this Court noted that "[w]hile an expert who is a urologist *may* testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert *must possess additional expertise* to offer expert testimony about what information should or should not be included in an IFU."[8] The Court has carefully considered Dr. Grier's qualifications about product warnings and found that he does not possess the expertise to offer testimony about what risks should be included in a product IFU.[9] Ethicon's Response Memorandum has not identified any new qualifications or expertise possessed by Dr. Grier since the Court last considered this issue.[10] As such, Dr. Grier's proposed expert testimony regarding product warnings, which includes expert testimony about the adequacy of the relevant IFUs should be excluded. To the extent necessary, the Plaintiffs incorporate their Wave 1 Memorandum as Exhibit A.

CONCLUSION

For reasons of the forgoing, the opinions of Dr. Grier, as set forth herein, must be excluded as they do not meet the standard governing expert opinion set forth by federal law.

Date: October 18, 2016.

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[8] Mem. Op. and Order (*Daubert* Motion re: Douglas Grier, M.D.), No. 2:12-md-02327, at 7-8 (S.D. W. Va. Aug. 31, 2016) [ECF # 2703] (emphasis added).
[9] *Id.*
[10] Defs' Brf. at 2-5.

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CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace